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STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]

DECISION
Case #: MPA - 206750

PRELIMINARY RECITALS

Pursuant to a petition filed on November 1, 2022, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Medicaid Services regarding Medical Assistance (MA), a hearing was held on December 22, 2022, by telephone.

The issue for determination is whether the agency correctly denied a Prior Authorization request (PA) for the drug Stelara.

There appeared at that time the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, WI 53703

By:

Division of Medicaid Services
PO Box 309
Madison, WI 53701-0309

ADMINISTRATIVE LAW JUDGE:

Beth Whitaker
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner (CARES #) is a resident of Monroe County who has been diagnosed with Crohn's disease

2. On October 14, 2022, [REDACTED] submitted a Prior Authorization request (PA) for the drug Stelara on petitioner's behalf, for treatment of Crohn's disease and prescribed by Dr. Daisy Batista, a gastroenterologist.
3. Petitioner has not used the drug Humira.
4. On October 19, 2022, the agency issues to the requesting pharmacy a notice of denial stating that the PA was denied because petitioner did not attempt the preferred drug Humira for at least three consecutive months and experience an unsatisfactory therapeutic response or experience a clinically significant adverse drug reaction. PA # [REDACTED]
5. On November 3, 2022, the Division received petitioner's request for hearing by U.S. Mail postmarked November 1, 2022.

DISCUSSION

Federal Medical Assistance rules do not require a state to cover prescription drugs; such coverage is at a state's option. 42 C.F.R. § 440.225. Effective October 1, 2004, the Division of Health Care Financing (DHCF) implemented a "Preferred Drug List" (PDL) Program for WI Medicaid and BadgerCare fee-for-service and SeniorCare as authorized by the State's biennial budget. Non-preferred drugs require prior authorization. Wis. Admin. Code § DHS 107.10. In evaluating a prior authorization request, the program considers the authorization standards at § DHS 107.02(3)(e). Those standards include the requirements that the requested service be a medical necessity, appropriate, and cost effective, and that the existence of less expensive alternative services be considered. *Id.* The petitioner bears the burden of proving that these standards are met.

In this case, the request involves the non-preferred drug, Stelara (ustekinumab). Stelara is a drug in the Cytokine and Cell-Adhesion Molecule (CAM) Antagonists PDL class. Cytokine and CAM antagonists are chemical mediators involved in inflammatory processes throughout the body. All non-preferred drugs in this PDL class require prior authorization since this is a class of drugs that entail utilization problems for the program. Wis. Admin. Code § DHS 107.10. Cytokine and CAM antagonist drugs are powerful biologic disease modifying agents that carry significant warnings regarding potential side effects, and treatment with these drugs usually costs \$5,000 or more per month.

In December 2020, physicians/prescribers and pharmacies were notified that the PDL policy, PA criteria, and PA forms for non-preferred cytokine and CAM antagonist drugs would be updated effective January 1, 2021. The updated publication included clinical criteria for PA requests for cytokine and CAM antagonist drugs for treatment of Crohn's Disease and Ulcerative Colitis. See, ForwardHealth update No. 2020-44, pp. 6-8.

Humira is a preferred drug used to treat Crohn's Disease. Preferred drugs do not require PA. The DMS clinical criteria for PA approval of a non-preferred Cytokine and CAM Antagonist Drug to treat Crohn's Disease are all of the following:

- The member has Crohn's disease.
- The prescription is written by a gastroenterologist or through a gastroenterology consultation.
 - The prescriber has indicated if the member has attempted any of the following drugs for Crohn's disease: 6MP, azathioprine, oral amino salicylates (balsalazide, mesalamine, olsalazine, or sulfasalazine), or methotrexate.
- The prescriber has indicated what other drugs the member has attempted for Crohn's disease (for example, antibiotics, glucocorticoids, or IV immunomodulators such as infliximab).

- The member has taken one preferred cytokine and CAM antagonist drug for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.
- The prescriber has indicated the clinical reason(s) why a non-preferred cytokine and CAM antagonist drug is being requested.

Id.

The request was denied because she did not try Humira first. Petitioner's physician Daisy Batista wrote on July 28, 2022, that petitioner should not have to try Humira before being prescribed Stelara because she was previously treated with Cimzia and then another biologic drug, Entyvio, and failed to improve with either. The physician opined that Stelara has a different mechanism of action than anti-TNFs and anti-integrin therapies and that it would not make sense clinically to give petitioner another anti-TNF drug given the failure of the anti-TNF biologic Cimzia.

The agency addressed Dr. Batista's reasoning:

"The preferred drug Humira, is an anti-TNF drug, similar to Cimzia. There are several anti-TNF drugs approved by the FDA for Crohn's disease (Cimzia, Humira, Remicade). ForwardHealth would not waive a trial of Humira simply because a member has had a trial with a similar agent."

ForwardHealth will waive trials with a preferred drug if there is adequate evidence to justify an exception, however, failure with an anti-TNF drug does not automatically warrant the change to a drug in a different class. The agency concluded that in this case the prescriber did not provide evidence related to the member's inadequate response with Cimzia to justify waiving a trial with Humira. The agency has elected not to waive the requirement to try Humira based on the evidence presented to it, including Dr. Batista's letter. I have no evidence in this record to show that there is a specific basis, beyond the undisputed fact that Cimzia and Humira are both anti-TNF drugs, to order the agency to waive the trial of Humira. They are two different drugs and the agency is reasonable and within its authority to require either an unsuccessful trial of Humira or additional evidence about the nature of the lack of success with Cimzia to establish that the requirement for a trial of Humira should be waived.

CONCLUSIONS OF LAW

Petitioner does not meet the criteria for coverage of the drug Stelara. The agency correctly denied the PA request.

THEREFORE, it is

ORDERED

That the petition for review is dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 4822 Madison Yards Way, 5th Floor North, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and

why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, **and** on those identified in this decision as “PARTIES IN INTEREST” **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

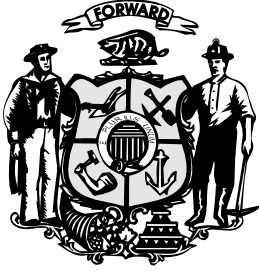
The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 11th day of January, 2023



\s _____

Beth Whitaker
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on January 11, 2023.

Division of Medicaid Services